

Remarks

Status of Claims

Claims 27-33 are pending in the application upon entry of the present amendments. The claims are supported in the claims as originally filed, and at least in the specification at paragraphs 57, 60 and 61 and in the Examples. No new matter has been added.

Amendment to the Specification

The specification has been amended to correct obvious typographical errors. The amendments do not contain new matter.

Claims Rejections: 35 U.S.C. §112, 1st Paragraph

In the Office Action dated October 18, 2007, claims 27-33 were rejected under 35 U.S.C. §112, first paragraph, as allegedly being non-enabled.

Specifically the Office Action asserts that “the claims are not limited to any controls, which would distinguish TRAIL-dependent from TRAIL-independent apoptosis activity.”. (See, Office Action page 6).

In addition, the Office Action asserts that “The specification does not demonstrate that any other agent than JIK-specific RNAi was identified by the instant claimed method. The specification is not enabling for a method that would allow one of ordinary skill in the art to identify any agent that meets all the limitations of the instant claims much less which could be practiced in a subject.”. (See, Office Action, pages 7-8).

With regard to distinguishing TRAIL-dependent from TRAIL-independent apoptosis, the Applicants respectfully disagree and respectfully assert that the specification discloses the methodology to distinguishing TRAIL-dependent from TRAIL-independent apoptosis. (See, for example, paragraphs 60 and 84). Therefore the Applicants respectfully assert that the claimed methods are enabled. However, without conceding to the rejection, and to expedite prosecution of the pending application, the Applicants have amended claim 27 to include contacting a first cell system with an agent and then with TRAIL, and also contacting a second cell system with the agent in the

absence of TRAIL, thereby distinguishing TRAIL-dependent from TRAIL-independent apoptosis. No new matter has been introduced and support for the amendment is found in paragraphs 60 and 84 of the specification as filed.

With regard to the specification being allegedly not enabling for a method that would allow one of ordinary skill in the art to identify any agent that meets all the limitations of the instant claims, other than JIK-specific RNAi, the Applicants respectfully disagree and respectfully assert that because only an enabling disclosure is required, Applicants need not describe all actual embodiments (MPEP § 2164.02). Furthermore, “[a] patent need not teach, and preferably omits, what is well known in the art” (MPEP § 2164.01).

The Applicants respectfully assert that by using siRNA based loss of function screening, the inventors discovered a number of genes (e.g., *JIK*) that impact TRAIL-induced apoptosis. (See, specification at paragraph 14 and Examples). Therefore, based on the discovery that *JIK* modulates TRAIL-induced apoptosis, then various test agents that modulate JIK kinase (the *JIK* expression protein) activity can be screened as agents that modulate TRAIL-induced apoptosis. In particular, the claimed methods comprise first identifying an agent that modulates the kinase activity of JIK, and confirming its effect on TRAIL-induced apoptosis activity. The Applicants respectfully assert that the specification discloses various test agents that can be screened using the claimed method, (See, specification at paragraphs 34-43 and Examples), and that a test agent can be screened to determine whether kinase activity is modulated by the test agent. (See, specification at paragraph 31). The Applicants respectfully assert that one of ordinary skill in the art would be able to use the method as claimed herein to identify any agent that modulates JIK kinase activity and thereby modulates TRAIL-induced apoptosis. Thus, the Applicants respectfully assert that the test agents in the claims are not limited to siRNA used to identify genes associated with TRAIL.

For each of the above reasons, Applicant respectfully submits that the claimed methods are enabled, and requests that this rejection be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants believe all claims now pending in this Application are in condition for allowance, and reconsideration and allowance is respectfully requested.

A fee of \$1,050.00 for a three (3) month extension of time is necessary in connection with this paper. It is believed that a total of \$1,050.00 is due, however if this is incorrect and additional fees are due, or additional extensions of time are necessary to prevent abandonment of this application, then the U.S. Patent and Trademark Office is authorized to deduct any requisite fees from, or deposit any overpayment into, Deposit Account **No. 50-1885** referencing docket No. P1111US10

If the Examiner believes a telephone conference would expedite prosecution of this application, the Examiner is respectfully requested to contact the undersigned at the telephone number below.

Respectfully submitted,

Date: April 10, 2008

/Daniel E. Raymond, Reg. # 53,504/

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